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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,626	12/18/2000	Satoshi Nakagawa	249-125	2229

7590 05/10/2002

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EXAMINER
SIEW, JEFFREY

ART UNIT	PAPER NUMBER
1637	9

DATE MAILED: 05/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/738,626	NAKAGAWA ET AL.	
	Examiner	Art Unit	FILE
	Jeffrey Siew	1656	

-- The MAILING DATE f this communication appears on the c ver sheet with the corresp ndence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *69-110* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 69 & 70, drawn to array and method of using, classified in class 435, subclass 287.2.

II. Claims 71-74, drawn to DNA sequence, classified in class 536, subclass 22.1.

III. Claims 75 & 77, drawn to polypeptide, classified in class 530, subclass 300.

IV. Claims 76 & 78, drawn to antibody, classified in class 530, subclass 386.

V. Claims 79-83 , drawn to method of using computer to identify target sequence, classified in class 702, subclass 19.

VI . Claim 84,86,88,90,92,94 & 96, drawn to polypeptide with replaced Val 59 residue of SEQ ID NO:6952, classified in class530, subclass 300.

VII. Claim 85,87,89,91,93 & 95, drawn to polypeptide with replaced Pro 458 residue of SEQ ID 4265, classified in class 530, subclass 300.

VIII. Claims 97-108 , drawn to method of breeding coryneform bacterium, classified in class 435, subclass 69.1.

IX. Claim 109, drawn to method of identifying a protein from amino acid sequence, classified in class 702, subclass 19.

X. Claim 110, drawn to 702, classified in class 435, subclass 252.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I through IX are each unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions.

Group I is drawn to array and method of using the array in which the array contains combination of at least two polynucleotides. The polynucleotide array differs from Group II-IX which are drawn to isolated DNA sequences , polypeptides or methods of using polypeptide sequences, antibodies, computer methods or cell culture in that the array may be distinctly used for quantitative nucleic expression and detection assays. Therefore, the above inventions are novel and unobvious over each other.

Group II is drawn to isolated DNA sequence and differs Group I & III-IX which are drawn to arrays, polypeptides or methods of using polypeptide sequences, antibodies and computer methods or cell cultures in that the isolated DNA sequence may be distinctly used as probe for labeling in Southern detection. Therefore, the above inventions are novel and unobvious over each other.

Group III is drawn to polypeptides and differs Group I, II & IV-IX which are drawn to either arrays, methods of using polypeptide sequences for analyzing sequence, antibodies and computer methods and cell cultures in that the polypeptide may be distinctly used in antigen production. Moreover, polypeptides and nucleic acids have distinct chemical structures and physical properties, the former composed of amino acids and the latter composed of nucleotides. Therefore, the above inventions are novel and unobvious over each other.

Group IV is drawn to antibody and differs Group I-III & V-IX which are drawn to arrays, isolated nucleic acid sequence, polypeptides or methods of using polypeptide sequences, computer methods or cell culture in that the antibody may be used in ELISA detections. Moreover, antibodies have distinct chemical structures and physical properties from other polypeptides and nucleic acids. Therefore, the above inventions are novel and unobvious over each other.

Group V is drawn to computer method of analyzing nucleic acid and differs Group I-IV & VI-IX which are drawn to arrays, isolated nucleic acid sequences, polypeptides or methods of using polypeptide sequences, antibodies or cell culture in that the computer method employs a computer to compare different sequences. Therefore, the above inventions are novel and unobvious over each other.

Group VI is drawn to specific polypeptide with a mutation at Val 59 and differs Group I-V & VI-IX which are drawn to arrays, isolated nucleic acid sequences, non mutated polypeptides or methods of using polypeptide sequences, antibodies or cell culture in that the mutated polypeptide has a distinct structural mutation that leads to changes in function. Therefore, the above inventions are novel and unobvious over each other.

Group VII is drawn to specific polypeptide with a mutation at Pro 458 and differs Group I-V & VI-IX which are drawn to arrays, isolated nucleic acid sequences, non mutated polypeptides or methods of using polypeptide sequences, antibodies or cell culture in that the mutated polypeptide has a distinct structural mutation that leads to changes in function. Therefore, the above inventions are novel and unobvious over each other.

Group VIII is drawn to method of breeding coryneform bacterium and differs Group I-VII & IX which are drawn to arrays, isolated nucleic acid sequences, non mutated polypeptides or methods of using polypeptide sequences and antibodies. The method of breeding employs a particular use of nucleic acid sequence which differs from the isolated nucleic acid sequence which may be employed in other probe or detection assays. Moreover, the method may be used to make a plurality of different types of coryneform bacterium. Therefore, the above inventions are novel and unobvious over each other.

Group IX is drawn to identifying proteins through analyzing and comparing amino acid sequences and differs Groups I-VIII & X which are drawn to arrays, isolated nucleic acid sequences, non mutated polypeptides, antibodies or cell cultures in that the separation of proteins and comparison of amino acid structures is required. Therefore, the above inventions are novel and unobvious over each other.

Group X is drawn to a specific cell culture and differs Group I-IX which are drawn to arrays, isolated nucleic acid sequences, non mutated polypeptides or methods of using polypeptide sequences and antibodies in that the cell culture comprises a unique chromosomal composition. Therefore, the above inventions are novel and unobvious over each other.

2. **Furthermore Group I contains an almost infinitesimal number of possible different combinations, applicant is required to select one combination and examination will proceed accordingly to MPEP 803.04.**

Sequence Election Requirement Applicable to Groups II-V, VIII & IX

3. In addition, each Groups *II-V, VIII & IX* detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Furthermore, the sequence searching in multiple expansive databases has put undue burden on the examiner and office resources. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **up to** ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Moreover, applicant is reminded that appropriate claim cancellation and amendments will be required on selection of group which contain dependent claims.

CONCLUSION

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

JEFFREY SIEW
PRIMARY EXAMINER

May 8, 2002